

Exhibit 80

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Follow the Money: Pain, Policy, and Profit

by John Fauber, Reporter, Milwaukee Journal Sentinel/MedPage Today
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The Federation of State Medical Boards, often develops guidelines that serve as the basis for model policies with the stated goal of improving medical practice -- but after its guideline for the use of opioids to treat chronic pain patients was adopted as a model policy, it asked Purdue Pharmaceuticals for \$100,000 to help pay for printing and distribution that policy to 700,000 practicing doctors.

That \$100,000 was just a small downpayment on the \$3.1 million that the Federation's foundation estimated it would cost for its campaign to get out the word about "safe" use of opioid analgesics in treatment of chronic pain.

The federation, which functions as a trade group representing some 70 allopathic and osteopathic medical boards, won't say how much money it received from industry, but the \$100,000 request was detailed in a document obtained by the Milwaukee Journal Sentinel/MedPage Today from University of Wisconsin School of Medicine and Public Health.

Why a Pain Policy?

Why the FSMB would turn to a pharmaceutical company to underwrite the cost of producing and distributing a book about its opioid prescribing policy -- and why the FSMB undertook developing such a policy in the first place -- is part of a much larger story that has unfolded over the last decade, culminating with the Centers for Disease Control and Prevention's stark warning about [spiraling risk of death from prescription painkillers](#).

An FSMB spokesperson said there were many reasons for it to codify a position on the prescribing of opioids, and among those reasons was a project supported by the Robert Wood Johnson Foundation to seek some common ground in the treatment of chronic pain.

A Journal Sentinel/MedPage Today investigation suggests it was the \$693,000 grant from the Robert Wood Johnson Foundation to University of Wisconsin that started the ball rolling down this slippery slope. That grant went to the UW Pain & Policy Studies Group.

Last year, the Journal Sentinel/MedPage Today reported that the UW Pain group had received \$2.5 million from Purdue and several other opioid makers between 1999 and 2010.

After the story ran last April, the UW Pain group said it had decided to stop taking money from the drug industry.

But that decision does not change the time line for the FSMB pain management policy -- at nearly every step along the way, financial connections between the FSMB policy and companies that make the drugs can be found.

For example:

- The RWJ-funded project started with an advisory committee that recruited several pain experts who had ties to makers of opioids -- a core group that included J. David Haddox, DDS, MD, then a member of the Purdue Pharma speakers' bureau, who went on to become a Purdue employee. Purdue is the maker of OxyContin.
- FSMB's involvement started with a guideline written in 1998, and then with its model policy, which was adopted in 2004. With that policy in hand, the FSMB decided to spread the word to the nation's physicians by translating the policy into a book and it delegated that task to Scott Fishman, MD, a University of California Davis physician with extensive financial ties to pharmaceutical companies that market opioids.
- FSMB not only asked Purdue for money, it also reached out to a total of six opioid makers for money to produce and distribute "Responsible Opioid Prescribing: A Physician's Guide," but it won't disclose how much each company contributed.
- In 2009 the University of Wisconsin School of Medicine and Public Health decided to offer an online CME course based on the FSMB book, and to fund the activity it sought and received a \$119,000 grant from Endo Pharmaceuticals (one the six companies that chipped in to pay for the book's printing and distribution). As course reviewer, UW chose Aaron Gilson, PhD, a UW employee, who had been paid to help another opioid maker, Cephalon, with a new drug application to the FDA.

Policy Prompting Practice

Deborah Grady, MD, a professor of medicine at the University of California, San Francisco, said she believes the federation's policy as well as CME courses such as the one offered by UW contributed to the marked increase in opioid use.

That policy also helped establish the idea that denying high doses of opioids to patients is a bad medical practice, she said.

"The sad fact is that for many patients, the pain is never controlled, despite very high, dangerous doses of opioids that may actually result in more side effects than benefit," Grady said.

The model policy, which describes how opioids should be used to treat pain, has been adopted in full or in part by nearly 30 state medical boards.

Instead of protecting patients from over-prescribing doctors, many of those medical boards have been "duped" by the federation's "pharma-funded campaign" into encouraging aggressive prescribing, said Andrew Kolodny, MD, a New York psychiatrist, addiction specialist and critic of the opioid industry.

States that want to go after pill mill operators and reckless doctors are unable to do so because they've adopted the policy, he added.

What's more, many of those medical boards purchased the opioid guide book and gave it to doctors, he said.

He said the book promotes aggressive prescribing. More than 160,000 copies of the book have been distributed.

In a statement, Lisa Robin, the federation's chief advocacy officer, said its efforts are not intended to advocate for opioid therapy.

"Far from encouraging opioid use, the policy and book have provided a much-needed warning to physicians that opioids are potentially dangerous, that the use of opioids for other than legitimate medical purposes poses a threat to the individual and society ... Such medications must be used with great caution."

She said the policy urges physicians to seek balance, "recognizing the fact that millions of legitimate patients rely on these medications for pain relief, while incorporating safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances."

Several doctors contacted for this story were critical of the book because it failed to point out the lack of science supporting the use of opioids for chronic, non cancer pain. Instead, the book says the drugs may be essential for chronic pain.

In a statement, UW said the book and the CME course are not clinical practice guidelines. They are a response to the issue of opioid abuse and how to reduce it, said UW spokeswoman, Lisa Brunette.

The book's content was reviewed for accuracy and balance by 20 experts, including 14 who had no financial relationships with drug companies, she said.

She said Gilson, who reviewed UW's CME course, is a widely published expert on pain policy issues. He had no financial relationship to the Endo Pharmaceuticals, which funded the course, she said.

In a statement, Fishman, the book's author, said he was not paid for his work on the book and does not receive royalties.

He acknowledged that when the first edition of the book was written in 2006, the science on the effectiveness of opioids "was not robust" and data on the severe risks "had yet to emerge."

Since then, new data on risks, including unintended overdose deaths, have emerged, he said.

The new risk information will be included in an expanded version of the book that will be published by the spring, he said.